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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,499	07/24/2003	Manne Satyanarayana Reddy	U 014732-3	1978

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03/02/2005

Ladas & Parry
26 West 61 Street
New York, NY 10023

EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,499

Applicant(s)

REDDY ET AL.

Examiner

Celia Chang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-33 are pending.
2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in INDIA on JULY 24, 2002. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).
Therefore, the benefit of the priority date can not be granted.
3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential element, such omission amounting to unclear and indefinite condition of the process. See MPEP § 2172.01. The omitted element is the pressure unit of the hydrogen pressure. Please note that the numerical number without unit does not define the required condition for such step.
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-6, 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,649,765.

See claim 1 and detailed exemplification and description on columns 3-4, examples 1-2. Vidyadhar et al. '765 disclosed all the elements of the claims in very explicit description (see examples 1-2 with anticipatory temperature, solvents, reagents and steps) with limited genus i.e. platinum or palladium oxide for which only platinum oxide was exemplified. In view of the very small genus, anticipation was found. Ex parte A, 17 USPQ2d 1716; In re Arkley 172 USPQ 524, In re Sivaramakrishnan 213 USPQ 441; In re Schaumann 197 USPQ 5.

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-6, 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vidyadhar et al. US 6,649,765 in view of Sugimoto et al. US 4,895,841.

Determination of the scope and content of the prior art (MPEP §2141.01)

Vidyadhar et al. '765 disclosed the process of making the instant formula I using formula IV and hydrogenation to form formula VI (see example 1), then alkylation of formula VI to get formula I (see example 2) with same pressure, temperature and solvents (see col. 3 lines 24-39), and choices of catalysts selected from platinum or palladium oxide.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the exemplified process and the instant claims is that only the preferred catalyst platinum oxide was exemplified. Sugimoto et al. '841 disclosed variation of processes in making analogous compounds of formula I including formula I. It was taught that the hydrogenation in structurally analogous compounds employed catalyst of similar type and palladium-carbon provides favorable results (see col. 14 lines 36-40).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above references provided variations of conditions in carrying out process of making compound of formula I with clear guidance and examples of the preferred embodiment with explicit suggestion of operability in choices of analogous catalysts. One skilled in the art would be motivated to choose the palladium catalyst as suggested in the prior art instead of the exemplified platinum oxide because as it is well known in the art that platinum oxide is costly,

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even though it gives the best mode. The choice of cost or efficiency is a design choice clearly delineated in the prior art.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-2, 4-6, 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vidyadhar et al. US 6,649,765 in view of Sugimoto et al. US 4,895,841 and Sugimoto et al. Bioorg. Med. Chem. Let. further in view of WO 97/22584.

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and 26). WO 97/22584 disclosed analogous process for making the same formula I compound wherein alternative solvents, temperature, and co-precipitation with ether have been clearly described (see p.18, examples 5-6, co-ppt line 23).

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above references provided variations of conditions in carrying out process of making compound of formula I with clear guidance and examples of the preferred embodiment with explicit suggestion of operability in choices of analogous catalysts. One skilled in the art would be motivated to choose the palladium catalyst as suggested in the prior art instead of the exemplified platinum oxide because as it is well known in the art that platinum oxide is costly, even though it gives the best mode. The choice of cost or efficiency is a design choice clearly delineated in the prior art.

The limitations in the dependent claims are alternative operating parameters clearly suggested in analogous art i. e. WO 97/22584 and demonstrated to be operable in similar steps are mere picking and choosing of an effect oriented parameter for maximum product yield which is prima facie obvious in the chemical art. In re Geisler 43 USPQ2d 1362. In re Aller 105 USPQ 233.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-2, , 4-6, 8-9, 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lensky US 5,606,064 in view of Sugimoto et al. US 4,895,841.

Determination of the scope and content of the prior art (MPEP §2141.01)

Lensky '064 disclosed very similar steps for a process of making compound of formula I, see examples 2, 4 and 6 wherein the exemplified catalyst is platinum dioxide with generic optional choices to palladium on carbon 9see col. 2 lines 16-18).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the continuous steps in examples 2, 4 and 6 is that instead of alkylation being performed at the last step, it was performed before hydrogenation. Sugimoto et al. '841 taught that palladium carbon would be an optional choice (col. 14 line 38-40) as well as N-alkylation is an optional choice (see K is hydrogen or alkyl etc. col. 2 lines 62-65)

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art would found picking the alternative palladium catalyst prima facie **because** the prior art explicitly suggested operability for palladium carbon. The changing of sequence for hydrogenation and alkylation is also prima facie obvious, since such derivatization steps are independent for different function groups. Especially, the prior art indicated the non-alkylated product is also desirable thus, suggested such independent sub-steps for derivatization of independent functional groups can be optional and in any sequence because they all will give the resulting product. Cohn v. Comm 148 USPQ 486.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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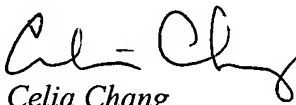
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Mar. 1, 2005


Celia Chang
Primary Examiner
Art Unit 1625